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UNITED STATES DISTRICT COURT

DISTRICT OF UTAH

UNITED STATES OF AMERICA, Plaintiff, v. PREMIUM PRODUCTION, LLC, a corporation, and RYAN PETERSEN, an individual, Defendants.	**COMPLAINT FOR PERMANENT INJUNCTION** Case No. 4:23-cv-00088-DN Judge David Nuffer

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin Premium Production, LLC, a corporation, and Ryan Peterson, an individual, (collectively, "Defendants") from:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction or causing to be introduced or delivered for introduction into interstate commerce articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of the current good manufacturing practice regulations for dietary supplements set forth in 21 C.F.R. Part 111 ("Dietary Supplement CGMP"); and

B. Violating 21 U.S.C. § 331(k), by doing acts to articles of food (dietary supplements, as defined by 21 U.S.C. § 321(ff)) while held for sale after shipment of one or more of their components in interstate commerce that results in the dietary supplements being adulterated within the meaning of 21 U.S.C. § 342(g)(1).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Premium Production, LLC ("Premium") is a limited liability company incorporated in Nevada and in Utah as a foreign limited liability company. Premium is located at 880 N Pinon St, Hildale, UT 84784 ("Defendants' Establishment"), within the jurisdiction of this Court. Defendant Premium manufactures three products labeled as dietary supplements, which are sold by Evig, LLC ("Evig") under the brand name Balance of Nature: (1) Whole Food Fiber & Spice, a powder, (2) Whole Produce Fruits, capsules, and (3) Whole Produce Veggies, capsules. These products are made using freeze dried fruits and vegetables, spices, and other

botanicals in powder form. As the manufacturer of these products, Defendant Premium is responsible for, among other things, testing raw components and finished products, and for packaging. Defendant Premium is also responsible for confirming the identity, purity, strength, and composition of the components and products and ensuring that all products and components meet specifications.

5. Defendant Ryan Peterson is the Manger at Premium and the most responsible person at the firm. He has all decision-making and oversight responsibilities over Premium and its employees.

6. Defendant Peterson performs his duties at Defendants' Establishment, within the jurisdiction of this Court**.**

DEFENDANTS' OPERATIONS

7. Defendants have been and are now engaged in the business of manufacturing and causing the distribution of food, namely dietary supplements within the meaning of the Act, 21 U.S.C. § 321(ff), from Defendants' Establishment.

DEFENDANTS DISTRIBUTE ADULTERATED DIETARY SUPPLEMENTS

8. It is a violation of the Act to introduce or deliver for introduction, or cause to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, or held under conditions that do not meet the Dietary Supplement CGMP regulations set forth at 21 C.F.R. Part 111. 21 U.S.C. § 331(a).

Defendants' Products are Dietary Supplements

9. A product is a dietary supplement within the meaning of the Act, if, among other things, it is "a product (other than tobacco) intended to supplement the diet" that contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any of them. 21 U.S.C. § 321(ff). In addition, a dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." *Id.*

Defendants' Products are Adulterated Dietary Supplements

10. The Act deems a dietary supplement to be adulterated if it is not prepared, packed, or held in conformance with "Dietary Supplement CGMP." *See* 21 U.S.C. § 342(g)(1), 21 C.F.R. Part 111.

11. The Dietary Supplement CGMP regulations are designed to ensure the quality of dietary supplements. The regulations apply to any person who manufactures, packages, labels, or (subject to an exception not relevant here) holds dietary supplements. The regulations require such persons to control all aspects of their processes and procedures to ensure compliance with established specifications for identity, purity, strength, composition, and limits on certain types of contamination.

12. FDA investigators most recently inspected Defendants' Establishment in May 2022 (the "2022 inspection"). This inspection established that the dietary supplements Defendants distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they

are prepared, packed, and/or held in a manner that does not conform to Dietary Supplement CGMP. Defendants' significant deviations from Dietary Supplement CGMP include, but are not limited to, the following:

A. Failure to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition, and for approving or rejecting any reprocessing, as required by 21 C.F.R. § 111.103. Specifically, Defendants have not established adequate Standard Operation Procedures ("SOPs") for their quality control operations. During the 2022 inspection, the Defendant Premium did not have any established SOPs. Following the 2022 inspection, Defendant Premium provided FDA with an SOP that merely outlined quality control responsibilities but did not provide sufficient information to show that Defendant Premium had adequate procedures in place for their quality control operations.

B. Failure to establish identity specifications and other specifications for each component that are necessary to ensure that the specifications for the identity, purity, strength and composition of dietary supplements manufactured using the components are met, as required by 21 C.F.R. § 111.70(b). Specifically, Defendants have not established identity specifications for the components used to manufacture the dietary supplements. During the 2022 inspection, Defendant Premium provided specification sheets for components, but the sheets did not establish adequate unique identity specifications for the components. Additionally, there were no other specifications for each component. Following the inspection, Defendant Premium provided FDA with specifications for three ingredients (papaya cube, orange powder, and carrot pieces)

but they did not contain identity specifications. Further, Defendant Premium did not provide any specifications on the numerous other ingredients contained in their products.

C. Failure to establish specifications for each dietary supplement manufactured for identity, purity, strength, and composition, as required by 21 C.F.R. § 111.70(e). Specifically, Defendants have not established specifications for finished product identity and strength. During the 2022 inspection, Defendant Premium had not established finished product specifications for the products. Following the inspection, Defendant Premium informed FDA that it uses organoleptic characteristics, i.e., smell, as the specification to identify the powdered ingredients that comprise the three Balance of Nature products. Organoleptic characteristics alone may not be used to test powdered or extracted botanicals for identity or strength. *See* 21 C.F.R. § 111.75(h)(1). Because the firm has not established specifications for finished product identity and strength, Defendant Premium is not able to test the firm's finished products and confirm specifications are met.

D. Failure to create master manufacturing records that included all requisite information, as required by 21 C.F.R. § 111. 210. Specifically, Defendants have not established adequate master manufacturing records ("MMRs"). During the 2022 inspection, Defendant Premium did not provide any actual MMRs, just batch records labeled as MMRs and which did not include any information on packaging, finished product specifications, or procedures for sampling. *See* 21 C.F.R. § 111. 210 (h). Following the inspection, Defendant Premium provided FDA with MMRs for the Fiber & Spice, Fruits, and Veggies, but they were inadequate in that they merely contained lists of ingredients without weight information and did not include sampling plans, specifications, and other required information. *See Id*., 21 C.F.R. § 111. 210 (d).

13. For the foregoing reasons, Defendants' products are adulterated dietary supplements within the meaning of 21 U.S.C. 342(g)(1). Defendants violate 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1).

14. Defendants violate 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined by 21 U.S.C. § 321(ff)) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

DEFENDANTS ENGAGE IN INTERSTATE COMMERCE

15. Evig, the distributor of the Balance of Nature products manufactured by Premium, primarily sells the products through its website, www.balanceofnature.com. Evig distributes approximately 85% of the finished product to customers out of state, including to Pennsylvania and California. Such shipments constitute the introduction or delivery for introduction into interstate commerce. Thus, Defendants, as the manufacturer of the products, cause the introduction or delivery for introduction, into interstate commerce, adulterated dietary supplements under 21 U.S.C. § 331(a).

16. In addition, Premium receives approximately 95% of the raw materials used to manufacture their products from suppliers out of state, including from Illinois, Wisconsin, California, and India. Such shipments satisfy the interstate commerce element under 21 U.S.C. § 331(k).

DEFENDANTS' HISTORY OF VIOLATIVE CONDUCT

17. Defendants have a long history of failing to comply with the Act. FDA has documented a pattern of continued violative conduct during multiple inspections of Defendants' Establishments and have repeatedly warned Defendants that such conduct could lead to enforcement action.

18. FDA conducted the most recent inspection of Defendants' Establishment in May 2022. As a result of the inspection, FDA issued a List of Inspectional Observations ("Form FDA 483") to Defendant Premium on May 27, 2022.[1] The Dietary Supplement CGMP violations described in Paragraph 12 were near repeats of observations included in a previously issued Form FDA 483.[2] Defendant Premium responded to the Form FDA 483 on June 13, July 8, August 5, 2022, and December 14, 2022. FDA found all of Defendant Premium's responses to be inadequate in addressing FDA's concerns. Defendant Premium's responses lacked sufficient detail and supporting documentation.

19. FDA previously conducted an inspection of Defendants' Establishment in March 2021. As a result of the inspection, FDA issued a Form FDA 483 to Defendant Premium on April 2, 2021[3]. The 2021 Form FDA 483 issued to Defendant Premium included repeat observations from a previously issued Warning Letter. Defendant Premium responded to the Form FDA 483 on April 21, 2021, which FDA found to be inadequate.

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[1] FDA issued an Amended Form FDA 483 to Defendant Premium on July 25, 2022.

[2] The 21 C.F.R. § 111. 210 violation described in Paragraph 14 involving the failure to create adequate master manufacturing records was revised from the 2021 Form FDA 483, which included a similar observation that covered the same issue.

[3] FDA issued an Amended Form FDA 483 to Defendant Premium on July 26, 2021.

20. FDA also previously conducted an inspection of Defendants' Establishment in 2019. As a result of the inspection, FDA issued a Warning Letter to Defendant Premium on July 29, 2019. The Warning Letter described Dietary Supplement CGMP violations that would be observed in the 2021 and 2022 Form FDA 483s.

21. Defendants continue to operate their businesses in a state of non-compliance. Defendant Premium's responses to FDA's issued Form FDA 483s have all been inadequate. All of Defendants' significant violations were near repeats from the 2021 inspection or 2019 Warning Letter.

22. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done, any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered or introduction, into interstate commerce articles of food (including but not limited to dietary supplements and their components) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1);

B. Violating 21 U.S.C. § 331(k), by doing acts to articles of food (dietary supplements, as defined by 21 U.S.C. § 321(ff)) while held for sale after shipment of one or

more of their components in interstate commerce that results in the dietary supplements being adulterated within the meaning of 21 U.S.C. § 342(g)(1).

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from manufacturing, preparing, processing, packing, holding, and distributing food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) at or from the Establishment, or at or from any other location(s) at which Defendants manufacture, prepare, process, pack, label, hold, and/or distribute food (dietary supplements), now or in the future, unless and until Defendants bring their manufacturing, preparing, processing, packing, holding, and distributing operations into compliance with the Act and Dietary Supplement CGMP regulations in a manner that has been found acceptable by FDA, and unless and until Defendants have otherwise brought their operations into compliance with the Act;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business, and all records relating to introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of any dietary supplement, or to holding for sale after shipment of one or more of their components in interstate commerce, to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

Dated this 11th day of October, 2023.

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